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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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| 09/448,868 | 11/24/99 | NI | J 1488.1300004 |

HM12/0706
STERNE KESSLER GOLDSTEIN AND FOX PLLC
SUITE 600 1100 NEW YORK AVENUE NW
WASHINGTON DC 20005-3934

| | |
|------------|--------------|
| EXAMINER | |
| KAUFMAN, C | |
| ART UNIT | PAPER NUMBER |

1646
DATE MAILED:
07/06/01

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/448,868

Applicant(s)

NI ET AL.

Examiner

Claire M. Kaufman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 April 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22-83 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 22-83 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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Election/Restrictions**Restriction Requirement:**

Applicants election of Group I, represented by claims 22-42, 44-64, 66-73 and 75-82 in paper number 10 filed 4/30/01, with traverse, is acknowledged. The traversal is on the ground(s) that the examination of the entire application would not constitute a burden to search. This is not found persuasive because contrary to Applicants' assertion that any search of the prior art in regard to Group I will reveal whether any prior art exists as to Group II (claims 43, 65, 74 and 83), a search is directed to references which would render the invention obvious, as well as references directed to anticipation of the invention, and therefore requires a search of relevant literature in many different areas of subject matter. Therefore, restriction is proper.

Applicants' request for rejoinder of Groups I and II once claims of Group I are found allowable is noted. Applicants are advised that at such time as the elected product claim(s) are indicated as being allowable, rejoinder of claims drawn to methods of using such may be requested pursuant to the procedures set forth in the Official Gazette notice dated March 26, 1996 (1184 O.G. 86). Such rejoinder is *not* tantamount to a withdrawal of the restriction requirement.

Upon reconsideration of Group I, it is concluded that the claims within Group I are drawn to numerous patentably distinct antibodies binding patentably distinct protein sequences. Thus, further restriction *within* the formerly presented Group I is required, as follows:

The claims are drawn to numerous patentably distinct antibodies, each of which constitutes a patentably distinct product. Applicants are required to elect a single invention of an antibody which specifically binds the polypeptide selected from the group consisting of the following regions of SEQ ID NO:2 (i.e. elect an antibody that binds a polypeptide from the following Markush group): Residues 1-468 (including the polypeptide encoded by the human cDNA of ATCC Deposit No. 97853), 24-468, 24-238, 132-221, 35-92, 114-160, 169-240, 239-264, 265-468, 267-298, 330-364, 391-404, 418-465 and 379-422.

Applicants should note that in some cases multiple claims encompass one of the patentably distinct inventions set forth herein, for example it is presumed by the Examiner in setting forth this requirement that the protein encoding by the nucleic acid of ATCC deposit

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97853 is SEQ ID NO: 2. To be fully responsive to this requirement, Applicants are **required** to point out which claims correspond to the elected invention.

Although the classifications for these various antibodies are the same (530/388.22) each represents a patentably distinct product with distinct physical and functional characteristics. Further the search for more than one product would be burdensome because each is claimed not by antibody sequence but by the sequence of the protein to which it binds, and requires a search of the corresponding region of the protein of SEQ ID NO: 2. Also, it is not known which amino acid sequence(s) within SEQ ID NO:2 make up epitopes so that each fragment could have one or more than one unique epitope. Further, for antibodies made to a denatured protein of SEQ ID NO:2, small stretches of amino acids (*e.g.*, 6) within SEQ ID NO:2 can constitute an antibody binding site, requiring an individual "word" search within the recited polypeptide fragments. Accordingly, restriction is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Claire M. Kaufman, whose telephone number is (703) 305-5791. Dr. Kaufman can generally be reached Monday through Thursday from 8:30AM to 12:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached at (703) 308-6564.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. NOTE: If applicant *does* submit a paper by fax, the original signed copy should be retained by the

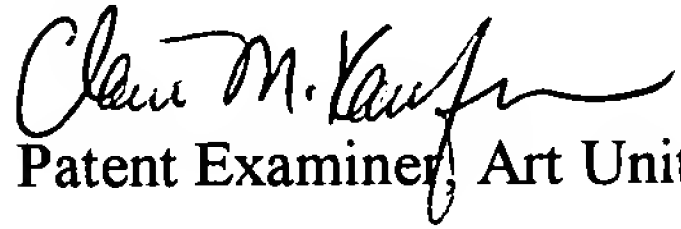
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applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office. **Please** advise the examiner at the telephone number above before facsimile transmission.

Claire M. Kaufman, Ph.D.

A handwritten signature in cursive script, appearing to read "Claire M. Kaufman", written in black ink.

Patent Examiner, Art Unit 1646

July 3, 2001